FEB - 2 2004 K033506

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Tracy J. Bickel
Regulatory Associate

Proprietary Name: Comprehensive Humeral Fracture Positioning Sleeve

Common Name: Centering Sleeve

Classification Name:

- Prosthesis, shoulder, non-constrained, metal/polymer cemented prosthesis (888.3650)
- Shoulder joint metal/polymer semi-constrained cemented prosthesis (888.3660)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Bio-Modular Centering Sleeve (K032507): Biomet, Inc.
- Comprehensive Humeral Fracture Stem (K023063): Biomet, Inc.

Device Description: The Comprehensive Humeral Fracture Positioning Sleeve is composed of Polymethylmethacrylate (PMMA) and is used in conjunction with the Comprehensive Humeral Fracture System (K023063). The device is a sleeve that fits over the distal tapered stem of the Comprehensive Fracture system and stops at a point below the fins of the stem.

Intended Use: The Comprehensive Humeral Fracture Positioning Sleeve is indicated for 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) Rheumatoid arthritis; 3) Revision where other devices or treatments have failed; 4) Correction of functional deformity; 5) Fractures of the proximal humerus, where other methods of treatment are deemed inadequate; and 6) Difficult clinical management problems, including cuff arthopathy, where other methods of treatment may not be suitable or may be inadequate.

Summary of Technologies: The Comprehensive Humeral Fracture Positioning Sleeve is to be used in conjunction with the stem in the previously cleared Comprehensive Humeral Fracture System. The sleeve holds the stem in the center of the canal as well as allowing the sleeve and stem to be raised and lowered in the canal. The Comprehensive Humeral Fracture Positioning sleeve is similar to or identical in terms of material, function, labeling, and sizing to the predicate device(s).

Non-Clinical Testing: An engineering justification was utilized to determine that no additional mechanical testing was required.

Clinical Testing: None provided as a basis for substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tracy J. Bickel
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 45681-0587

FEB - 2 2004

Re: K033506
Trade/Device Name: Comprehensive Humeral Fracture Positioning Sleeve
Regulation Number: 21 CFR 888.3660; 888.3560
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis;
Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, KWT
Dated: November 4, 2003
Received: November 5, 2003

Dear Ms. Bickel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Division Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033506

Device Name: Comprehensive Humeral Fracture Positioning Sleeve

Indications For Use:

The Comprehensive Humeral Fracture Positioning Sleeve is indicated for

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2) Rheumatoid arthritis;
3) Revision where other devices or treatments have failed;
4) Correction of functional deformity;
5) Fractures of the proximal humerus, where other methods of treatment are deemed inadequate; and
6) Difficult clinical management problems, including cuff arthopathy, where other methods of treatment may not be suitable or may be inadequate.

For Cemented Use Only

Prescription Use __X__ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** ______ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

storative
Neurological Devices
Number K033506